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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,835	08/04/2003	Tedd E. Elich	9280.2	5061

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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,835	ELICH ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 16-22* is/are pending in the application.

4a) Of the above claim(s) *4-7,9 and 16-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8 and 10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/17/03&7/26/05*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 1/12/06 is acknowledged.

Election

2. Applicant's election with traverse of Group I claims 1-13 SEQ.ID.NO: 2 (Ustilago), is acknowledged.

The traversal is on the grounds that

(1) the restriction requirement between group I and groups III-VI is not reasonable because claims of Groups III-VI depend, either directly or indirectly on claim 1 and no additional searching would be required to examine these claims together.

(2) The claims of groups III-IV are related to the claims of group I as methods of use of a claimed product, a reasonable number of which should be searched with the product claim

(3) Applicant traverse the restriction requirement among distinct and patentably different inventions SEQ.ID.NOS: 2, 4, 6, 8 etc because the invention, as defined by generic claim 1, involves the deletion of a biotin binding and carboxy transferase domains, and not merely the discovery of a new Acetyl CoA carboxylase. Applicant states while SEQ .ID. NO: 2 is one example of deletion, the invention is exemplified by other species, and other species are "linked" by generic and "linking" claim1.

This is not found persuasive because

(1) MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (a) independent or distinct as claimed and (b) a serious search and examination burden is placed on the examiner if restriction is not required. The term "distinct" is defined to "mean that two or more subjects as disclosed are related, for example, as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, the inventions of the

Groups are drawn to distinct inventions which are related as separate products capable of separate manufacture, use or sale as described in the previous Office Action. Restriction between the inventions is deemed to be proper for the reasons previously set forth.

The examiner would like to bring applicants attention to group II, claims 14 and 15 drawn to DNA. Applicant agrees with the examiner that group II is distinct and different from that of groups I and III-VI. Therefore, cancelled claims 14 and 15 (see reply filed on 1/12/06) although they depend on "generic" claim 1. However, applicant traverse the restriction requirement between groups I, III-VI because they directly or indirectly depend on claim 1. As discussed in the previous office action examiner restricted claims based on the structure, property and function of the products, even though they depend on claim 1.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of the Groups are classified separately necessitating different searches of issued U.S. Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because, for example, search and examination issues for nucleic acid vaccines are different and would not encompass protein vaccines. Additionally, it is submitted that the inventions of the separate Groups have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

(2) The examiner will rejoin the withdrawn method (one) claims (16-17) that depend from or otherwise include all the limitations of the allowable product claim in accordance with the provisions of MPEP 821 .04.

(3) Applicants indicate that with respect to the species election, they elect SEQ ID NO -2. It is specifically noted, that a species election was not imposed. Each of the recited sequences was deemed patentably distinct from each other and applicants were required to elect a single product for examination on the merits.

The examiner disagrees because deletions of biotin binding and carboxy transferase domains do not link polypeptide of different species since they have different structure or function or property as indicated above in the restriction. As such, examination of the single product is restricted to the SEQ ID NO: 2 as it is related to Ustilago ACCase BC domain and is structurally different and distinct from other transferases obtained from mammal, insect, yeast, Ascomycota, Basidiomycota and Oomycota.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

3. Claims 14-15 have been cancelled.

Claims 1, 2, 3, 8 and 10-13 are under examination as applicant elected invention SEQ.ID.NO: 2. Therefore, claims drawn to 4-7 and 9 are withdrawn drawn to non-elected invention in the polypeptide group-I.

Claims 4-7, 9 and 16-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non elected groups III and IV inventions. However, When claims directed to the product, polypeptide is found allowable, withdrawn method (only one method) claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821 .04.

Priority

4. This application 10/633,835 claims Priority from Provisional Application 60/401,170 filed on 08/05/2002.

Information Disclosure Statement

5. Information Disclosure Statements filed on 11/17/03 and 7/26/05 are acknowledged and a signed copy of each is attached to this Office action.

Claim rejections 35 U.S.C. 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3, 8 and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing as the metes and bounds of the claim are not clear because a peptide comprises an Acetyl COA carboxylase (ACCase) that includes biotin binding domain, and carboxy transferase domain and a functional biotin carboxylase (BC) domain. However, the claim also requires a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase (BC) domain. Therefore, the metes and bounds of the claim unclear.

Claim I is vague in reciting, "having a functional biotin carboxylase (BC) domain" because it is unclear how an ACCase still comprise (i. e, having) a functional biotin carboxylase (BC) domain after having deleted biotin binding domain and carboxy transferase domain? It appears from the specification that isolated ACCase comprises biotin binding domain, carboxy transferase domain, and biotin carboxylase (BC) domain. Therefore, after having deleted biotin binding domain and deleted carboxy transferase domain, the ACCase should consist a biotin carboxylase (BC) only.

Claim interpretation

Claim 1 is interpreted as a peptide having functional biotin carboxylase (BC) domain only since biotin binding domain, and a carboxy transferase domain are deleted. In other words a peptide ACCase having BC only. Therefore, it is viewed as a peptide comprising BC domain only.

Claim Rejections - 35 USC 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -- -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Waldrop et al Biochemistry; 1994; *33*(34) pp 10249 - 10256;

Waldrop et al disclose protein crystals of biotin carboxylase (see page 10250, left column, under materials and methods; crystallization, figure 2 and figure 3), having no biotin-binding domain (i.e., deleted), having no carboxy transferase domain (deleted) as shown in figure 2 and 3. Therefore, the prior art anticipated claim 1.

Relevant Prior Art

10. The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

Bailey et al Mol Gen Genet (1995) 249: 191-201(IDS 11/17/03):

Bailey teaches an isolated recombinant protein Acetyl COA carboxylase (ACCase) protein having 2185 amino acids from *Ustilago maydis* (see figure 4). Further the art identifies a biotin binding domain, carboxy transferase domain, and a functional biotin carboxylase domain

of ACCase. (see figure 5 and page 198, left column). The art indicates that the ACCase is required for essential cellular growth (processes) other than fatty acid biosynthesis (see figure 6 and page 198, right column).

Vahlensieck et al U.S.Patent 5641,666:

Vahlensieck et al teach mutation at position 77 in yeast ACCase BC leads to drug/antibiotic resistance i.e., soraphen A resistant yeast (soraphen A drug resistant). Thus the art teaches the binding site for developing resistance is located in BC. Further, the art teaches methods of isolating a gene that encodes soraphen resistant biotin carboxylase enzyme (see abstract and columns 2-4 for example US 5641666). Thus the art identified the key component of biotin carboxylase domain that is involved in soraphen A drug resistance. The art suggests that this site can be used in assays to identify inhibitors of soraphen A resistant ACCase.

Kimura, Journal of Bacteriology, October 2000, Vol. 182, No. 19, p. 5462-5469:

Kimura et al teach *Myxococcus xanthus* biotin carboxylase subunits of acetyl coenzyme A (acetyl-CoA) carboxylases. The fragment contained two open reading frames (ORF1 and ORF2), designated the *accB* and *accA* genes, capable of encoding a 538-amino-acid protein of 58.1 kDa and a 573-amino-acid protein of 61.5 kDa, respectively. The protein (AccA) encoded by the *accA* gene was strikingly similar to biotin carboxylase subunits of acetyl-CoA and propionyl-CoA carboxylases and of pyruvate carboxylase. An *accA* disruption mutant showed a reduced growth rate and reduced acetyl-CoA carboxylase activity compared with the wild-type strain. Western blot analysis indicated that the product of the *accA* gene was a biotinylated protein that was expressed during the exponential growth phase.

Levert et al, Biochemistry, 39 (14), 4122 -4128, 2000:

Levert teaches Biotin carboxylase from *Escherichia coli* catalyzes the ATP-dependent carboxylation of biotin and is one component of the multi enzyme complex acetyl-CoA carboxylase.

Schulte et al 1997 Proc. Natl. Acad. Sci. USA Vol. 94, pp. 3465-3470:

Schulte et al disclose an isolated BnACCaseg1 peptide (class II.I) fragment comprising only functional biotin carboxylase domain (see page 3469, left column, first para, figure 5, T07923 and figure 2, line 3) .The art also teaches peptide comprising BC domain from other organisms including yeast etc (figure4).

Remarks

11. No claims are allowed.

Conclusion

12. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600